IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Hassan, *et al.*
Assignee: Banner Pharmacaps, Inc.
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Art Unit: 1615

For: ENTERIC PREPARATIONS

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

AMENDED APPEAL BRIEF UNDER 37 C.F.R. §41.37

Sir:

This amended brief is submitted pursuant to 37 C.F.R. §41.37 in support of the Notice of Appeal filed in the above-captioned application on August 17, 2009 and in response to the Notification of Non-Compliant Appeal Brief mailed November 11, 2009. If any fees are required in connection with this paper, the Commissioner is hereby authorized to charge the necessary fees to Deposit Account No. 09-0528.

I. REAL PARTY IN INTEREST – 37 CFR §41.37(c)(1)(i)

The real party in interest in this appeal is the assignee, BANNER PHARMACAPS, INC. of North Carolina.

II. RELATED APPEALS AND INTERFERENCES – 37 CFR §41.37(c)(1)(ii)

There are no other appeals or interferences known to Appellants, Appellants' legal representative or assignee which may be related to, directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

II. STATUS OF CLAIMS – 37 CFR §41.37(c)(1)(iii)

Claims 20 and 24–40 are pending in the application. Claims 20 and 24-40 stand rejected. The rejection of claims 20 and 24-40 is appealed. Claims 1-19 were canceled in the Amendment filed July 22, 2008. Claims 21-23 were canceled in the Amendment filed April 16, 2008.

IV. STATUS OF AMENDMENTS – 37 CFR §41.37(c)(1)(iv)

No amendments after final have been requested or entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER – 37 CFR §41.37(c)(1)(v)

The sole independent claim is claim 20, which reads as follows:

> An enteric soft capsule shell formed from a gel mass composition comprising
>
> a) a film-forming, water-soluble polymer,
>
> b) an acid-insoluble polymer; and
>
> c) an alkaline aqueous solvent;
>
> wherein the ratio of acid-insoluble polymer to film-forming, water soluble polymer is from about 30:70 to about 45:55 by weight; the final pH of the gel mass is less than or equal to about 9 pH units; and the moisture content of the enteric soft capsule shell formed from the gel mass composition is from about 2% to about 10%.

Accordingly, all pending claims are directed to an enteric soft capsule shell formed from a gel mass composition (see, *e.g*, page 3, lines 28-29) that includes (a) a film-forming, water-soluble polymer (see, *e.g*, page 3, lines 26-27); (b) an acid-insoluble polymer (see, *e.g*, page 3, lines 26-27), and (c) an alkaline aqueous solvent (see, *e.g*, page 4, lines 10-12). In the gel mass composition, the ratio of the acid-insoluble polymer to film-forming, water soluble polymer is from about 30:70 to about 45:55 by weight (see, *e.g*, page 4, line 32 to page 5, line 1; and page 15, lines 24-27). In addition, the final pH of the gel mass from which the soft capsule shell is formed is less than or equal to about 9 pH units (see, *e.g*, page 6, lines 29-30), and the moisture content of the shell is from about 2% to about 10% (see, *e.g*, page 4, line 29).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL – 37 CFR §41.37(c)(1)(vi)

The grounds for rejection to be reviewed on appeal are set forth in the final Office Action mailed May 19, 2009. Pending Claims 20 and 24-40 each stand rejected under 35 USC §103(a). Claim 20 stands rejected under 35 U.S.C. §103(a) as being unpatenable over Venkateswara et al. (PCT Application No. WO 01/24780; "Venkateswara") in view of Hirai et al. (U.S. Patent No. 3,826,666; "Hirai") and further in view of Matthews et al. (U.S. Patent No. 4,816,259; "Matthews"). Claims 24–25, 27–33, and 35–40 stand rejected under 35 U.S.C. §103(a) as being unpatenable over Venkateswara, in view of Okajima et al. (U.S. Patent No. 4,138,013; "Okajima"), in view of Hirai, and further in view of Matthews. Claim 26 stands rejected under 35 U.S.C. §103(a) as being unpatenable over Venkateswara, in view of Okajima, in view of Hirai, and further in view of Shank (U.S. Patent No. 4,500,453; "Shank"). Lastly, Claim 34 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Venkateswara, in view of Okajima, in view of Hirai, and further in view of Itoh (U.S. Patent No. 5,194,464; "Itoh").

VII. ARGUMENT – 37 CFR §41.37(c)(1)(vii)

All pending claims recite an enteric soft capsule shell formed from a gel mass composition that includes a film-forming water-soluble polymer, an acid-insoluble polymer, an alkaline aqueous solvent, and, optionally, a plasticizer. The ratio of the acid-insoluble polymer to the film-forming water soluble polymer is from about 30:70 to about 45:55 by weight. In addition; the final pH of the gel mass is less than or equal to about 9 pH units, and the moisture content of the enteric soft capsule shell formed from the gel mass composition is from about 2% to about 10%. .

As set forth below, Appellants believe that the Examiner has not established a *prima facie* case of obviousness regarding any of the pending claims. In addition or alternatively, even if the Examiner has established a *prima facie* case of obviousness (which Appellants do not hereby admit), Appellants present arguments herein that rebut *prima facie* obviousness. Accordingly, the rejections of all pending claims under 35 USC §103(a) are in error and must be reversed.

A. Summary of the Law

According to the Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 U.S.P.Q.2d 1385 (2007) ("*KSR*") and current USPTO Examination Guidelines, the proper objective analysis for determining obviousness under 35 U.S.C. § 103 is articulated in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17, 148 U.S.P.Q. 459 (1966) ("*Graham*"). *See generally*, Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in view of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526 (Oct. 10, 2007) ("Examination Guidelines") and U.S. Patent & Trademark Office, Manual Of Patent Examining Procedure, 8th ed., Revision 7 ("MPEP") § 2141. Under this construction, obviousness is a question of law based on underlying factual inquiries. The *Graham* factual inquiries enunciated by the Court include: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the claimed invention and the prior art; (3) resolving the level of ordinary skill in the pertinent art; and (4) evaluating evidence of secondary considerations.

In addition to the factors cited above, the following criteria must be met in order to establish a proper *prima facie* case of obviousness: (1) the prior art reference (or references, when combined) must teach or suggest *all* the claim limitations; *see In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); (2) the combination of references must teach the predictable use of prior art elements according to their established functions; *see KSR*, 550 U.S. at 417; and (3) there must be a reasonable expectation of success in combining the teachings of the references.

In *KSR*, the Court noted that the analysis supporting a rejection under 35 U.S.C. § 103(a) should be made *explicit*, and that it is "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art references]" in the manner claimed. The Court specifically stated:

> Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order

> to determine whether there was *an apparent reason* to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, *this analysis should be made explicit*.

KSR, 550 U.S. at 418, emphasis added; *citing In Re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds *cannot be sustained by mere conclusory statements*, instead, there must be some articulated reasoning with some rational underpinning to support a legal conclusion of obviousness"; emphasis added). Additionally, in ascertaining the differences between the claimed invention and the prior art, it is well established that a prior art reference must be considered in its entirety (i.e., as a whole), including portions of the reference that would lead away from the claimed invention. *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983). *See also* Examination Guidelines at 57528 and M.P.E.P. § 2141.02(VI). Thus, the key to supporting a rejection under 35 U.S.C. § 103(a) is clear articulation of the reasons why the claimed invention would have been obvious to a person having ordinary skill in the art at the time immediately prior to conception of the invention.

The Court in *KSR* also expressly stated that it is legally insufficient to conclude that a claim is obvious just because a feature of a claim can be independently shown in the art.

> A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

KSR, 550 U.S. at 418.

The Examiner has asserted that the references Hirai et al. (U.S. Patent No. 3,826,666), Matthews et al. (U.S. Patent No. 4,816,259), Okajima et al. (U.S. Patent No. 4,138,013), Shank (U.S. Patent No. 4,500,453), and Itoh (U.S. Patent No. 5,194,464), when combined with the primary reference, Venkateswara et al. (PCT Application No. WO

01/24780), teach every element of the claimed invention. As set forth below, the Examiner's assertion is unfounded because every element of the claimed invention is not taught or suggested by these references, either individually or when combined. Accordingly, the Examiner has not established a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

B. Independent Claim 20

Independent Claim 20 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Venkateswara et al. (PCT Application No. WO 01/24780; "Venkateswara") in view of Hirai, et al. (U.S. Patent No. 3,826,666; "Hirai") and further in view of Matthews et al. (U.S. Patent No. 4,816,259; "Matthews"). Appellants believe that the rejection of Claim 20 is in error for the reasons set forth below, and must be reversed.

1. Venkateswara does not teach a ratio of enteric (acid-insoluble) polymer to film-forming polymer.

The primary reference, Venkateswara, describes the production of soft gelatin capsules containing benzimidazole derivatives that are resistant to gastric juice. The Examiner has respectively misrepresented the disclosure of Venkateswara and used it to allege obviousness of the Appellants' claims. The secondary references, Hirai and Matthews, are not cited for any teaching or suggestion that cures the deficiencies of Venkateswara. Office Action mailed May 19, 2009, p. 3. Hirai is cited only for the alleged teaching relating to the pH of a gel mass. Matthews is cited only for the alleged teaching relating to moisture content of a capsule shell. Neither reference is cited for any teaching or suggestion of a ratio of acid-insoluble polymer to film-forming polymer. Accordingly, the cited teachings of the secondary references fail to cure the deficiencies of Venkateswara.

Specifically, the Examiner asserts that Venkateswara discloses the acid-insoluble polymer can be 40% by weight of the dried shell (p. 5, lines 25–27), and therefore is considered to be about 30:70 (42%)." Office Action mailed May 19, 2009, pp. 2–3. The cited lines of Venkateswara describe "a preferred embodiment" as follows: "The amount of such enteric polymer employed may range from 5.0–40.0 percent, preferably 5.0–25.0 percent by weight with

reference to the dried shell." However, contrary to the Examiner's assertion, this passage of Venkateswara does not teach or suggest a ratio of acid-insoluble polymer to film-forming polymer as required by Claim 20. Furthermore, the weight percentage given in the Venkateswara reference is that of the enteric polymer in the *dried shell*. Appellant's specification and claims refer to the ratio of the enteric polymer to the film-forming polymer in a gel mass composition before formation and drying of the capsule shell.

The Examiner's reasoning presumes that *every component* of the dried shell other than "enteric polymer" in a composition exhibiting the upper end of the recited range would be a "film-forming polymer" such as gelatin. Based on this assumption, the Examiner asserts that the "ratio" disclosed could be 40:60 and "is considered to be about 30:70 (42%)". This assertion is wholly unsupported in the reference, for at least the reason that the cited passage provides no information on the components or composition of the dried shell. Consequently, nothing regarding a *ratio* of acid-insoluble polymer to film-forming polymer is taught or suggested by the Venkateswara reference.

Further. analysis of the actual ratios of enteric polymer to gelatin in the Venkateswara reference supports Appellants' position. *See* Venkateswara, pp. 8–17. A review of the exemplified compositions presented in Venkateswara demonstrates that no ratio of enteric polymer to gelatin exceeds 10:30 (whole number: 0.333), compared to 30:70 (whole number: 0.43), which is the lowest end of the ratio range claimed by the Appellants. These ratios are substantially lower than those assumed by the Examiner based on the upper end of the recited percentage range of enteric polymer in the dried shell described in Venkateswara. The Examples provided in the Venkateswara reference, when converted to whole number ratios of enteric polymer to film-forming polymer, are completely outside the range claimed by the Appellants. *See* Venkateswara, pp. 8–17. Venkateswara teaches whole number ranges of enteric polymer to film-forming polymer from 0.188 (7.5:40) to 0.333 (10:30). In contrast, Appellants' claimed ranges are from 0.43 (30:70) to 0.82 (45:55), and thus are outside the ranges taught by Venkateswara. Consequently, the Venkateswara reference fails to teach or suggest *any* percentage or amount of enteric polymer in a defined ratio with the film-forming polymer. As

noted above, *no ratio whatsoever* is taught in the passage of Venkateswara quoted in the Office Action.

Furthermore, the Examiner **admits** that Venkateswara does not teach the ratio range claimed by the Appellants: "While Venkateswara et al. does not disclose an upper end of the ratio that is comparable to the instantly claimed ratios, it would be obvious for one of ordinary skill in the art to modify the amounts of water soluble polymer and acid-insoluble polymer present in the composition." *See* Office Action mailed May 19, 2009, p. 4. Thus, a critical claim element (the ratio of enteric polymer to film-forming polymer) is not found in Venkateswara. Therefore, Venkateswara, even when combined with the other cited references, does not teach, suggest or motivate production of the claimed enteric composition with a ratio of enteric polymer to film-forming polymer of 0.43 (30:70) to 0.82 (45:55). Further, the Examiner provides no reason or rationale why a person having ordinary skill in the art would attempt to modify the respective ratio of enteric and film-forming polymer, the pH level, or the moisture content of the composition to achieve the desired result.

Consequently, for the reasons set forth above, the Examiner has not established a *prima facie* case of obvious, and the rejection of claim 20 under 35 U.S.C. § 103(a) must be reversed.

2. Appellants' ratio of enteric polymer to film-forming polymer is critical under the alkaline formulation conditions.

Under no circumstances do Appellants admit or acquiesce that the Examiner has established a *prima facie* case of obviousness by asserting the following arguments. Nevertheless, even assuming that the Examiner has established a *prima facie* case of obviousness under 35 U.S.C. 103(a), the rejection should be reversed for at least the following reasons.

Appellants' disclosed ratio of enteric polymer to film-forming polymer, which approaches that disclosed by Venkateswara (i.e., 0.25 or 20:80 and 0.333 or 10:30, respectively), was shown to be the "minimal effective level" of enteric polymer to achieve acceptable enteric

results" and produced "border quality" compositions. *See* Application, p. 15, ll. 16–17 and ll. 22–24. Thus, the ranges taught by Venkateswara would not produce acceptable enteric stability in the Appellants' formulation. Consequently, Appellants have elucidated the **critical range** of the ratio of enteric polymer to film-forming polymer under the claimed composition conditions. *See* MPEP § 2144.05(III). Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness. MPEP § 7.02(a)(II). The presence of a property not possessed by the prior art is evidence of nonobviousness. ***In re Papesch***, 315 F.2d 381, 137 U.S.P.Q. 43 (C.C.P.A. 1963).

The Appellants in the subject application claim an enteric composition containing a defined ratio of enteric polymer to film-forming polymer that is capable of forming soft capsule shells where the final pH of the gel mass is less than or equal to about pH 9.0 and has a moisture content of about 2–10%. Neither Venkateswara nor any of the other cited references suggest or teach enteric capsule compositions wherein the final pH of the gel mass is less than or equal to about pH 9.0 or wherein the moisture content is about 2–10%. Thus, the claimed composition has unexpected properties not possessed by the cited references.

The Examiner cites *In re Aller*, 105 U.S.P.Q. 233 (C.C.P.A. 1955) as support for the assertion that "discovering the optimum or working ranges involves only routine skill in the art." *See* Office Action mailed May 19, 2009, p. 4. However, *Aller* also supports the proposition that "[u]nder some circumstances, however, changes [in conditions] may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art." *Aller*, 105 U.S.P.Q. at 235. In the present case, Appellants claim an enteric formulation with a ratio of acid-insoluble polymer to film-forming polymer of 30:70 to about 45:55 by weight, where the final pH of the gel mass is less than or equal to about pH 9.0 and the moisture content is about 2–10%. These conditions for forming enteric soft capsules are neither taught nor suggested by the Venkateswara reference nor any of the other cited references. As stated above, the Examiner does not provide a reason why a person having ordinary skill in the art would modify the respective ratios of enteric and film-forming polymers to achieve the desired result. Further, all of the elements of the claimed composition are interdependent and must be considered as a whole and not as

independent variables. All words in a claim must be considered in judging the patentability of a claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494 (C.C.P.A. 1970). *See* MPEP § 2143.03. Consequently, the rejection of Claim 20 under 35 U.S.C. § 103(a) is in error and must be reversed.

3. Venkateswara and Hirai teach away from the alkaline pH in the claimed composition.

Under no circumstances do Appellants admit or acquiesce that the Examiner has established a *prima facie* case of obviousness by asserting the following arguments. Nevertheless, even assuming that the Examiner has established a *prima facie* case of obviousness under 35 U.S.C. §103(a), the rejection should be withdrawn for at least the following reasons.

The Venkateswara and Hirai references both teach away from enteric capsule compositions wherein the final pH of the gel mass is less than or equal to about pH 9.0. Venkateswara teaches that "the resulting capsules being in aqueous medium [sic] up to a pH of 5.5 but quickly dissolving [sic] above pH of 6.0." *See* Venkateswara p. 5, ll. 3–4; 14–15; 17–18; etc. The Examiner mistakenly asserts that Hirai discloses that the "final pH of the gel mass is less than or equal to about 9 pH units. (col. 3, lines 12–13)." The actual statement in the Hirai specification in column 3, lines 12–13 is: "The pH of the solution should preferably be on the acid side and about the same as that of the gelatin itself." The phrase "acid side" in the statement indicates that the pH level should preferably be acidic, i.e., a pH value below 7.0. Further, the Examiner asserts that Hirai teaches that it "would have been obvious to one of ordinary skill in the art to modify the pH to prevent alteration of the gelatin (col. 3, lines 6–8)." *See* Office Action mailed May 19, 2009, p. 3. This statement is taken out of context and must be read with the surrounding portions of the specification. The appropriate section from the Hirai specification, encompassing column 3, lines 4–13 is:

> In making this aqueous solution containing the salt of HPMCP[,] we prefer to use just enough alkali to effect the solution of the ester, as any excess alkali present in the final solution tends to destroy or alter the gelatin. However, if desired, an excess of alkali may be used and the excess alkali present in the resultant solution neutralized with acid before adding the gelatin; or the solution may be heated until the pH falls to the proper value.

> The pH of the solution should preferably be on the acid side and about the same as that of the gelatin itself.

Accordingly, Hirai does not teach that the pH should be less than or equal to about 9 pH units, but rather that alkaline solutions (i.e., those having a pH above 7.0) must be neutralized by the addition of acid or by heating. After such actions, the resulting solution should be acidic (i.e., the pH should be below 7.0). Clearly, this reference when combined with Venkateswara does not provide the claim element that "the final pH of the gel mass is less than or equal to about 9 pH units. Consequently, claim 20 is not obvious over Venkateswara alone or in view of Hirai, further in view of Matthews. Because Venkateswara does not teach a ratio of acid-insoluble polymer to film-forming polymer of 30:70 to about 45:55 by weight, there is no teaching, suggestion, or motivation to combine this reference with the Hirai or Matthews references to achieve the claimed enteric composition with a reasonable expectation of success.

Because neither Venkateswara and secondary references Hirai and Matthews do not teach all of the elements of Appellants' claimed composition, the rejection of Claim 20 under 35 U.S.C. § 103(a) is in error and must be reversed. Furthermore, even if the cited references disclosed all the elements of the claimed invention, the Examiner has failed to establish a rational reason for combining the references or that an artisan of ordinary skill would achieve success by combining these references. A statement that modifications of the references to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (B.P.A.I. 1993). *See* MPEP § 2143.01(IV). Without the present Application as a roadmap, one of ordinary skill in the art would not have had a reason to combine the cited references. Such hindsight reconstruction of a claimed invention is impermissible.

Accordingly, for at least the reasons that Venkateswara does not teach a ratio of enteric (acid-insoluble) polymer to film-forming polymer; Appellants' ratio of enteric polymer to film-forming polymer is critical under the alkaline formulation conditions; and Venkateswara and

Hirai teach away from the elevated pH values in the claimed composition, the rejection of Claim 20 under 35 U.S.C. §103(a) is in error and must be reversed.

C. Dependent Claims 24–25, 27–33, and 35–40

Claims 24–25, 27–33, and 35–40 stand rejected under 35 U.S.C. § 103(a) as being unpatenable over Venkateswara, in view of Okajima et al. (U.S. Patent No. 4,138,013; "Okajima"), in view of Hirai, and further in view of Matthews. For the reasons set forth below, the rejection of claims 24–25, 27–33, and 35–40 under 35 U.S.C. § 103(a) should be reversed.

In the final Office Action, Venkateswara, allegedly discloses an enteric soft capsule shell formed from a gel mass composition comprising a film-forming, water-soluble polymer, an acid-insoluble polymer, and an alkaline aqueous solvent. In addition, Okajima allegedly discloses a gel mass composition comprising a film-forming, water-soluble polymer, an acid-insoluble polymer, an alkaline aqueous solvent, a plasticizer (PEG), and optionally, a coloring agent. Hirai is cited by the Examiner for its alleged teaching relating to the pH of a gel mass. Matthews allegedly teaches the moisture content of a capsule shell.

As discussed in detail above, Venkateswara does not disclose the claimed ratio of enteric (acid-insoluble) polymer to film-forming polymer as required by base claim 20. In addition, none of secondary references, Okajima, Hirai and Matthews disclose such a ratio. Furthermore, Hirai teaches away from the alkaline pH of the claimed composition.

Specifically, none of Venkateswara, Okajima, Hirai, and Matthews, either independently or when combined, teaches or suggests an enteric soft capsule shell formed from a gel mass composition comprising a film-forming, water-soluble polymer, an acid-insoluble polymer, and an alkaline aqueous solvent, wherein the ratio of acid-insoluble polymer to film-forming, water soluble polymer is from about 30:70 to about 45:55 by weight, the final pH of the gel mass is less than or equal to about 9 pH units, and the moisture content of the enteric soft capsule shell formed from the gel mass composition is from about 2% to about 10% as recited in independent Claim 20.

Claims 24–25, 27–33, and 35–40 each depend from claim 20, and include every limitation thereof. As discussed above, base claim 20 is not obvious over the cited references. Thus, claims 24–25, 27–33, and 35–40 are also not obvious for the same reasons that base claim 20 is not obvious over the cited references. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *See In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988) and MPEP § 2143.03. Consequently, the rejection of claims 24–25, 27–33, and 35–40 under 35 U.S.C. §103(a) is in error and must be reversed.

D. Dependent Claim 26

Claim 26 stands rejected under 35 U.S.C. § 103(a) as being unpatenable over Venkateswara, in view of Okajima, in view of Hirai, and further in view of Shank (U.S. Patent No. 4,500,453; "Shank"). For the reasons set forth below, the rejection of Claim 26 is in error and must be reversed.

Venkateswara allegedly discloses an enteric soft capsule shell formed from a gel mass composition comprising a film-forming, water-soluble polymer, an acid-insoluble polymer, and an alkaline aqueous solvent. Okajima allegedly discloses a gel mass composition comprising a film-forming, water-soluble polymer, an acid-insoluble polymer, an alkaline aqueous solvent, a plasticizer (PEG), and optionally, a coloring agent. Hirai is cited for the alleged teaching relating to the pH of a gel mass. Shank allegedly teaches that gelatin is from animal bones and that hard enteric capsules are made with gelatin having about 100-250 blooms.

As discussed in detail above, Venkateswara fails to teach or disclose a ratio of enteric (acid-insoluble) polymer to film-forming polymer as required by base Claim 20, and none of the secondary references Okajima, Hirai and Shank includes any teaching or suggestion that cures the deficiencies of Venkateswara. Furthermore, Hirai teaches away from the alkaline pH of the claimed composition.

Specifically, none of cited references Venkateswara, Okajima, Hirai, and Shank, either independently or when combined, teaches or suggests an enteric soft capsule shell formed from a

gel mass composition comprising a film-forming, water-soluble polymer, an acid-insoluble polymer, and an alkaline aqueous solvent, wherein the ratio of acid-insoluble polymer to film-forming, water soluble polymer is from about 30:70 to about 45:55 by weight, and wherein the final pH of the gel mass is less than or equal to about 9 pH units, and the moisture content of the enteric soft capsule shell formed from the gel mass composition is from about 2% to about 10%.

Claim 26 depends from claim 20, and includes every limitation thereof. As discussed above, base claim 20 is not obvious over the cited references. Thus, claim 26 is nonobvious for the same reasons that claim 20 is not obvious over the cited references. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *See In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988) and MPEP § 2143.03. Consequently, the rejection of claim 26 under 35 U.S.C. §103(a) is in error and must be reversed.

E. Dependent Claim 34

Claim 34 stands rejected under 35 U.S.C. § 103(a) as being unpatenable over Venkateswara, in view of Okajima, in view of Hirai, and further in view of U.S. Patent No. 5,194,464; "Itch"). For the reasons set forth below, the rejection of Claim 34 is in error and must be reversed.

The Office Action mailed May 19, 2009 states that Venkateswara allegedly discloses an enteric soft capsule shell formed from a gel mass composition comprising a film-forming, water-soluble polymer, an acid-insoluble polymer, and an alkaline aqueous solvent. The final Office Action also alleges that Okajima discloses a gel mass composition comprising a film-forming, water-soluble polymer, an acid-insoluble polymer, an alkaline aqueous solvent, a plasticizer (PEG), and optionally, a coloring agent. Hirai is cited for the alleged teaching relating to the pH of a gel mass, and Itoh allegedly teaches using a mixture of ethanol and water as a solvent to dissolve hydroxypropyl methylcellulose phthalate.

As discussed in detail above, Venkateswara does not teach or disclose a ratio of enteric (acid-insoluble) polymer to film-forming polymer as required by base Claim 20. In addition, none of the secondary references, Okajima, Hirai and Itoh includes any teaching or suggestion

that cures the deficiencies of Venkateswara. In addition, Hirai teaches away from the alkaline pH of the claimed composition.

Specifically, none of Venkateswara, Okajima, Hirai, and Itoh, either independently or when combined, teaches or suggests an enteric soft capsule shell formed from a gel mass composition comprising a film-forming, water-soluble polymer, an acid-insoluble polymer, and an alkaline aqueous solvent, wherein the ratio of acid-insoluble polymer to film-forming, water soluble polymer is from about 30:70 to about 45:55 by weight, and wherein the final pH of the gel mass is less than or equal to about 9 pH units, and the moisture content of the enteric soft capsule shell formed from the gel mass composition is from about 2% to about 10% as required by base claim 20.

Claim 34 depends from claim 20 and includes every limitation thereof. As discussed above, base claim 20 is not obvious over the cited references. Thus, claim 34 is nonobvious for the same reasons that claim 20 is not obvious over the cited references. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *See In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988) and MPEP § 2143.03. Consequently, the rejection of claim 34 under 35 USC §103(a) is in error and must be reversed.

VIII. CLAIMS APPENDIX – 37 CFR §41.37(c)(1)(viii)

A copy of the pending claims involved in this appeal is appended hereto.

IX. EVIDENCE APPENDIX – 37 CFR §41.37(c)(1)(ix)

No evidence has been submitted pursuant to 37 CFR §§ 1.130, 1.131 or 1.132 or entered by the Examiner and relied upon by Appellants in this appeal.

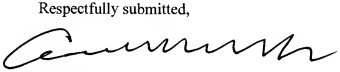
X. RELATED PROCEEDINGS APPENDIX – 37 CFR §41.37(c)(1)(x)

There are no related proceedings.

XI. CONCLUSION

In light of the foregoing arguments, Appellants maintain that the Examiner has failed to establish a *prima facie* case that Claims 20 and 24–40 would have been obvious to a person of ordinary skill in the art at the time of the claimed invention. In addition or alternatively, even if the Examiner has established a *prima facie* case of obviousness of Claims 20 and 24–40 (which Appellants do not hereby admit), Appellants have set forth arguments that rebut a *prima facie* case of obviousness. Accordingly, Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the rejections of claims 20 and 24–40 under 35 U.S.C. § 103(a) and remand the case to the Examiner for allowance of all pending claims.

Respectfully submitted,



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CLAIMS APPENDIX - 37 CFR §41.37(c)(1)(viii)

The claims involved in the appeal are as follows:

20. An enteric soft capsule shell formed from a gel mass composition comprising

a) a film-forming, water-soluble polymer,

b) an acid-insoluble polymer; and

c) an alkaline aqueous solvent;

wherein the ratio of acid-insoluble polymer to film-forming, water soluble polymer is from about 30:70 to about 45:55 by weight; the final pH of the gel mass is less than or equal to about 9 pH units; and the moisture content of the enteric soft capsule shell formed from the gel mass composition is from about 2% to about 10%.

24. The enteric soft capsule shell of claim 20, wherein the film-forming, water-soluble polymer is proteinaeous.

25. The enteric soft capsule shell of claim 24, wherein the proteinaeous film-forming, water-soluble polymer is gelatin.

26. The enteric soft capsule shell of claim 25, wherein the gelatin is extracted from animal bones or skins, and has about 100 to about 250 blooms.

27. The enteric soft capsule shell of claim 20, wherein the film-forming, water-soluble polymer is a carbohydrate.

28. The enteric soft capsule shell of claim 27, wherein the carbohydrate is selected from the group consisting of hydroxypropyl methylcellulose and methyl cellulose.

29. The enteric soft capsule shell of claim 20, wherein the acid-insoluble polymer is selected from the group consisting of acrylic and methacrylic acid copolymers, cellulose acetate esters such as phthalate, butyrate, hydroxypropyl methyl cellulose phthalate, and salts thereof.

30. The enteric soft capsule shell of claim 20, further comprising at least one plasticizer selected from the group consisting of sorbitol, glycerol, polyethlene glycol, poly-alcohols with 3 to 6 carbon atoms, citric acid, citric acid esters, triethyl citrate, and combinations thereof.

31. The enteric soft capsule shell of claim 20, wherein the alkaline aqueous solution comprises an alkali selected from the group consisting of ammonia, sodium hydroxide, potassium hydroxide, ethylenediamine, hydroxylamine, and tri-ethanolamine.

32. The enteric soft capsule shell of claim 20, wherein the alkaline aqueous solution comprises a volatile alkali.

33. The enteric soft capsule shell of claim 32, wherein the volatile alkali is selected from the group consisting of ammonia and ethylenediamine.

34. The enteric soft capsule shell of claim 20, wherein the alkaline aqueous solution is a hydroalcoholic solution.

35. The enteric soft capsule shell of claim 20, where the final pH of the gel mass is less than or equal to about 8.5.

36. The enteric soft capsule shell of claim 20, wherein the enteric soft capsule shell has a moisture content of from about 2% to about 10%.

37. The enteric soft capsule shell of claim 36, wherein the moisture content is from about 4% to about 8%.

38. The enteric soft capsule shell of claim 36, wherein the moisture content is about 8%.

39. The enteric soft capsule shell of claim 20, wherein the gel mass compositions comprises a plasticizer, and the ratio of plasticizer to film-forming, water-soluble polymer is from about 1:9 to about 1:1 by weight.

40. The enteric soft capsule shell of claim 39, wherein the ratio of plasticizer to film-forming, water-soluble polymer is about 1:3 by weight.

EVIDENCE APPENDIX – 37 CFR §41.37(c)(1)(ix)

(None)

RELATED PROCEEDINGS APPENDIX – 37 CFR §41.37(c)(1)(x)

There are no related proceedings.